



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,130	05/14/2001	Keith H.S. Campbell	105434.105001	8898

7590 04/16/2007
Sherry M. Knowles
KING & SPALDING
191 Peachtree Street N.E. 45th Floor
Atlanta, GA 30303

EXAMINER

BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
----------	--------------

1632

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/600,130

Applicant(s)

CAMPBELL, KEITH H.S.

Examiner

Valarie Bertoglio

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 28 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-47, 49, 50, 56-63, 66-76, 83-88 and 90-92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-47, 49, 50, 56-58, 66-76, 83-88 and 90-92 is/are rejected.
- 7) ☒ Claim(s) 59-63 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Examiner for the instant application is now Valarie Bertoglio, AU1632.

Applicant's reply dated 09/13/2005 was received 07/28/2006 along with a petition to withdraw abandonment. This petition was not granted but the subsequent petition, 11/28/2006 was granted. Thus, prosecution is hereby reopened and Applicant's reply received 07/28/2006 is currently under consideration.

Claims 1-41,48,51-55,64-65,77-82,89 and 93-113 have been cancelled. Claims 42-47,49-50,56-63,66-76,83-88 and 90-92 are pending and under consideration in the instant office action.

Claim Objections

Claims 59-63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 69 is objected to because of the following informalities: Claim 69 reads "animal a fetus" at step (b) and step (c) rather than "animal fetus". This appears to be a typographical error. Appropriate correction is required.

Claim 57 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Double Patenting

The objection to claims 89 and 93-113 under 37 CFR 1.75 as being substantial duplicates of other pending claims is rendered moot by the cancellation of claims 89 and 93-113.

Applicant is advised that should claim 88 be found allowable, claim 91 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 42-47, 49-50, 56-58, 66-76, 83-87 and 90-92 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of reconstituting a non-primate mammal practicing steps (i)-(iv), does not reasonably provide enablement for use of the claimed method with any animal, including primate species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The

rejection is maintained for reasons of record set forth at pages 4-6 of the office action dated 04/13/2005.

The rejection is withdrawn as it relates to claims 59-63,88 and 90-92 as these claims are limited to non-primate species.

Applicant's arguments have been fully considered and are not persuasive.

Applicant notes that reconstituted embryos can have uses other than producing an animal, including production of ES cells or other cell types (see paragraph bridging pages 6-7 of Applicant's remarks received 07/28/2006). Applicant argues that Hwang *et al.* (2004) reported the derivation of a pluripotent ES cell line from a cloned human blastocyst via somatic cell nuclear transfer. Applicant says primate embryos and primate pluripotent mammalian cells derived therefrom have been produced via nuclear transfer.

In response, Applicant's arguments are not persuasive with respect to cloned primate embryos. As noted by both Simerly [*Science*, 300:297, 2003] and by Vogel [*Science*, 300:225-227, 2003], primate cloning had not been attainable using somatic cells because cells fail to undergo proper cell division. Vogel states that a few cell divisions occur before the developmental program is "hopelessly derailed" (paragraph bridging columns 1-2, page 225). Proteins necessary for proper cell division are removed upon removal of the oocyte nucleus in primates, but not other mammals, as these proteins are not localized with the chromosomes in non-primate mammals (page 225, col. 2, paragraph 2). Furthermore, with respect to the teachings of Hwang 2004), this paper was retracted by *Science* magazine as containing fabricated data (see *Science*, 311:335, 2006). Thus, the art, well after the date of filing of the instant application, teaches that even the earliest events in cloning a primate from a somatic cell are hindered and the

Art Unit: 1632

mechanisms underlying this were not fully understood such that one could make a primate nuclear transfer embryo even to early blastocyst stages having cells competent to form a cell line.

Applicant also argues that Lanza *et al.* support that, in terms of cloning efficiencies of other mammalian species, Simerly *et al* (2003) failed to attempt enough nuclear transfers to deem it “unachievable”. In response, while the efficiency of cloning in any species is very low and that a very large number attempts must be made to meet success, this fact fails to overcome the findings in the art that primate cells fail to undergo proper cell division following somatic cell nuclear transfer. The teachings of Simerly (2003) and Vogel (2003) support an underdeveloped nature and very high degree of unpredictability in the art of cloning primates at the time the instant application was filed. The failure to clone a primate even to early embryonic stages does not appear to be a matter of inefficiency but to a difference in oocyte morphology and cell division that requires undue experimentation to characterize and overcome. While it is agreed that this does not render primate cloning “unachievable” for the future, it clearly supports the unpredictability of success and lack of guidance in the art, as well as the specification, at the time the application was filed.

It is noted that Applicant’s arguments are not relevant to claims 45,46 and 69-76 as they require development of an embryo to term.

It is also noted that the claims are broadly drawn to any species of animal, including non-mammals such as birds, fish, and insects. The art of somatic cell transfer as referred to in the specification, relates to mammalian species. Cloning by somatic cell nuclear transfer has not

Art Unit: 1632

been developed as broadly encompassed by the claims and is not supported by the specification. Therefore, the instant claims should be limited to non-primate mammals, rather than, animals.

New Matter

The rejection of claims 89 and 93-113 as introducing new matter into the specification is rendered moot in light of Applicant's cancellation of the claims.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57 and 71-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 57 is unclear because it is required that the first oocyte of claim 42 be enucleated. However, step ii of claim 42 requires removal of the nucleus from the oocyte. Thus, the relationship between claim 57 and 42 is not clear.

The terminology “further manipulated” in claims 71 and 72 is unclear. It is not known what kind of manipulation is being referred to or what is intended to be encompassed by the claims. It is also unclear in claim 71, whether the phrase “prior to full development of the embryo” means development to the last embryonic stage just prior to becoming a fetus or whether it is referring to full development into a born offspring. Likewise, claim 72 is further unclear because it is not clear whether the phrase “prior to full development of the fetus” means

Art Unit: 1632

development to the last fetal stage just prior to becoming a live-born offspring or whether it is referring to full development into a born offspring.

Claims 73 and 74 are unclear. The claims refer the method of claim 69, wherein a cell line is derived from the embryo or fetus of the claims. It is not clear if the claims encompass preparing the animal of claim 69 (see preamble of claim 69 and step c), if at steps (a) or (b), the embryo or fetus is used to make a cell line.

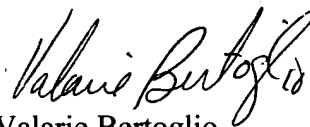
Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Valarie Bertoglio
Examiner
Art Unit 1632